

FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

2012 SEP 27 P 2:04
CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Plaintiff,

v.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for Intellectual
Property and
Director of the United States Patent and
Trademark Office
Office of General Counsel,
United States Patent and Trademark Office
Madison Building East, Rm. 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No. 1:12cv1090
LO/IDD

COMPLAINT

Plaintiff, Gilead Sciences, Inc. ("Gilead"), for its complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 8,148,374 ("the '374 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '374 patent be changed from 559 days to 616 days.

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedures Act, 5 U.S.C. §§ 701-706.

JURISDICTION AND VENUE

3. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361; 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

4. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

5. This Complaint is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

THE PARTIES

6. Plaintiff Gilead is a corporation organized under the laws of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California, 94404.

7. Defendant, the Honorable David J. Kappos (“Director”), is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“PTO”), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154.

BACKGROUND

8. United States patent application number 12/036,124 (“the ‘124 application”) was filed on February 22, 2008, and issued as the ‘374 patent on April 3, 2012. The claims of the ‘374 patent are directed to inhibitors of cytochrome P450 monooxygenase and methods of use of the inhibitors to treat a patient in need thereof. The ‘374 patent is attached as **Exhibit A**.

9. Plaintiff Gilead is the assignee of the ‘374 patent.

10. Under 35 U.S.C. § 154(b), the Director of the PTO must grant a patent term adjustment in accordance with the provisions of section 154(b), which states, in pertinent part,

that “[t]he Director shall proceed to grant the patent after completion of the Director’s determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.” 35 U.S.C. § 154(b)(3)(D).

11. In determining patent term adjustment, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO under 35 U.S.C. §§ 154(b)(1)(A), (B), and (C), as limited by the following: (i) any overlapping periods of PTO delay as specified by 35 U.S.C. § 154(b)(2)(A); (ii) any disclaimer of patent term by the applicant under 35 U.S.C. § 154(b)(2)(B); and (iii) any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

12. On July 29, 2011, the Director mailed a Notice of Allowance containing the Director’s provisional determination of 153 days of patent term adjustment pursuant to 35 U.S.C. § 154(b)(3).

13. On October 27, 2011, in accordance with 37 C.F.R. § 1.705(b), Plaintiff filed an Application for Patent Term Adjustment (“Application for PTA”) with the PTO to request correction of the Director’s patent term adjustment determination. The Application for PTA is attached as **Exhibit B**.

14. On March 1, 2012, the Director mailed a Decision on Application for Patent Term Adjustment (“Decision I”) dismissing Plaintiff’s Application for PTA. Decision I is attached as **Exhibit C**.

15. On April 3, 2012, the ‘374 patent issued reflecting the Director’s final determination of 559 days of patent term adjustment.

16. On April 30, 2012, Plaintiff filed a Petition Under 37 C.F.R. § 1.181(a)(3) to Invoke the Supervisory Authority of the Director (“181 Petition”). The 181 Petition is attached as **Exhibit D**.

17. On June 5, 2012, the Director mailed a Decision on Application for Patent Term Adjustment (“Decision II”) denying Plaintiff’s 181 Petition. Decision II is attached as Exhibit E.

18. Section 154(b)(4)(A) of Title 35 provides that “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such an action.” Section 702 of Title 5 further provides, in pertinent part, that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” Plaintiff Gilead hereby brings the present action for judicial review of the PTO’s calculation of patent term adjustment for the ‘374 patent.

CLAIM FOR RELIEF

19. The allegations of paragraphs 1-18 are incorporated into this claim for relief as if fully set forth herein.

20. The patent term adjustment for the ‘374 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth on the face of the patent, is 559 days. The determination of this 559 day patent term adjustment is in error because the PTO, and the Director acting in his official capacity, improperly calculated the length of the applicant delay period defined by 35 U.S.C. § 154(b)(2)(C).

21. The correct patent term adjustment for the ‘374 patent is 616 days.

22. Under 35 U.S.C. § 154(b)(1)(A), the correct number of days attributable to PTO examination delay (“A Delay”) is 245 days. The Director correctly calculated the A Delay.

23. Under 35 U.S.C. § 154(b)(1)(B), the correct number of days attributable to application pendency in excess of three years (“B Delay”) is 406 days. The Director correctly calculated the B Delay.

24. Under 35 U.S.C. § 154(b)(2)(C), the correct number of days of applicant delay is 0 days. An information disclosure statement was filed on April 16, 2010, subsequent to a response to restriction requirement filed on February 18, 2010. The Director incorrectly assessed 57 days of applicant delay for the period from February 19, 2010, to April 16, 2010. The information disclosure statement was filed before the mailing of a first office action on the merits (which occurred on May 13, 2010) and caused no delay in processing or examination of the application. It is contrary to the plain meaning of the controlling statutory provision, 35 U.S.C. § 154(b)(2)(C)(i), for the PTO to assess applicant delay for an information disclosure statement that is filed before a first office action on the merits and does not cause any delay in the processing or examination of an application. In addition to being contrary to the plain meaning of the statute, there is no rational basis for the PTO to selectively assess applicant delay for an information disclosure statement filed before the mailing of a first office action on the merits in only those cases (such as this one) where the first office action on the merits is preceded by a restriction requirement. There is no meaningful difference between an application that is subjected to a restriction requirement and one that is not that would justify the PTO’s differential treatment of information disclosure statements filed before a first office action on the merits. In both circumstances, an information disclosure statement filed before a first office action on the merits does not delay processing or examination of the application. The 57 days of

applicant delay assessed by the PTO from February 19, 2010, to April 16, 2010 should be adjusted to 0 days.

25. Section 154(b)(2)(A) of Title 35 provides that “to the extent that periods of delay attributable to grounds specified in paragraph [b](1) overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed.” The overlap between the A Delay period and the B Delay period in the prosecution of the ‘374 patent is 35 days. The Director correctly calculated the overlap between the A Delay period and the B Delay period.

26. The ‘374 patent is not subject to a disclaimer of term. Thus, the period of patent term adjustment is not limited under 35 U.S.C. § 154(b)(2)(B).

27. The correct patent term adjustment under 35 U.S.C. §§ 154(b)(1) and (2) is the sum of the A Delay and B Delay (245 days + 406 days = 651 days) minus the number of days of overlap of A Delay and B Delay (35 days) and applicant delay (0 days), for a net correct patent term adjustment of 616 days for the ‘374 patent.

28. Accordingly, the Director’s determination that the ‘374 patent is entitled to only 559 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation.

PRAYER FOR RELIEF

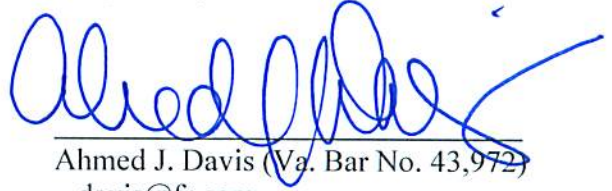
Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Judgment :

A. Changing the period of patent term adjustment for the ‘374 patent term from 559 days to 616 days, and requiring the Director to extend the term of the ‘374 patent to reflect the correct 616 day patent term adjustment.

B. Granting such other and future relief as the nature of the case may admit or require and as may be just and equitable.

Dated: September 27, 2012

Respectfully Submitted,



Ahmed J. Davis (Va. Bar No. 43,972)
davis@fr.com

Andrew R. Kopsidas, (*pro hac* admission
pending)
kopsidas@fr.com

FISH & RICHARDSON P.C.
1425 K Street, N.W.
Washington, D.C. 20005
Telephone: 202-783-5070
Facsimile: 202-783-2331

*Counsel for Plaintiff
Gilead Sciences, Inc.*